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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,820	06/27/2003	Robert J. Sweeney	279.635US1	8407
21186	7590	11/22/2006	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			SMITH, TERRI L	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,820	SWEENEY, ROBERT J.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 45-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-22 and 25-44 is/are rejected.
- 7) ☒ Claim(s) 23 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3-24-05; 12-9-05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of claims 14–44 in the reply filed on 23 October 2006 is acknowledged.
2. Applicant's amended claims filed on 23 October 2006 in answer to the Election Restriction are non-compliant because they fail to meet the requirements of 37 CFR § 1.121. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. The status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Cancelled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended). Applicant is required to correct the claim identifiers of the non-elected claims.

Information Disclosure Statement

3. The information disclosure statement filed 24 March 2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the publication dates for patent documents 5,682,900, 5,718,242, 6,370,430 and WO-97/39681 are incorrect and the first two documents listed in Non-Patent Literature Documents have an incorrect date (1st document) and no date (2nd document) listed. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement,

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including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

4. The disclosure is objected to because of the following informalities: On page 1 line 17, a serial number is missing. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 14–22 and 25–43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcus, U.S. Patent 4,637,400, and in view of Olson et al., U.S. Patent 5,779,645.

7. Regarding claims 14, 17, 18, 26, 36, 37, 41, 42 and 43 Marcus discloses receiving a sample series corresponding to a signal sampled at a predetermined rate (e.g. Figs. 5A, 5B and 6); for each sample in a sample series, calculating a curvature to form a curvature series using a processor (e.g. column 3, lines 12–13; column 6, lines 35–42; column 1, lines 49–51, 53–54 and 60–63); identifying a lobe in a curvature series (e.g. Fig. 5A where a lobe is defined by a turn as per Applicant's specification); calculating an area of a lobe (e.g. column 5, lines 41–46; column 6, lines 10–17 where area is the angle taken by the signal between the start of a turn and the end of a turn, and area is expressed in radians as per Applicant's specification); identifying a parameter for a lobe (e.g. Fig. 5A, element 13) and storing a characteristic point in a memory (column 6, lines 10–13). Marcus does not disclose an area greater than a predetermined value

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and a characteristic point including a time of a parameter and an amplitude corresponding to a time of a parameter. However, Olson et al. disclose an area greater than a predetermined value and a characteristic point including a time of a parameter and an amplitude corresponding to a time of a parameter (e.g. Fig. 2, element 212 a peak (amplitude) rises above a predetermined sensing threshold 216 represents an area greater than a predetermined value, element 202 represents time and element 212 (peak) represents amplitude) to reduce waveform complexity resulting in power conservation and extended battery life. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Marcus to include an area greater than a predetermined value and a characteristic point including a time of a parameter and an amplitude corresponding to a time of a parameter, as taught by Olson et al. to improve device performance for optimum therapy delivery.

8. Marcus discloses the essential features of the claimed invention as described above except for an electrocardiogram sampled at a predetermined rate (claim 16) and calculating a predetermined value as a function of changes in a sampled signal (claim 22) and storing a code as a function of the predetermined rate (claim 25). However, Olson et al. disclose an electrocardiogram sampled at a predetermined rate (column 3, lines 30–33) and calculating a predetermined value as a function of changes in a sampled signal (e.g. column 4, lines 26–29) and storing a code as a function of the predetermined rate (e.g. Figs. 8 and 9, elements 806 and 904) to provide ease of signal acquisition and reduce and simplify computational complexity. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Marcus to include an electrocardiogram sampled at a predetermined rate and calculating a predetermined value as a function of changes in a sampled

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signal and storing a code as a function of the predetermined rate, as taught by Olson et al. to render a robust and reliable device for administering therapy.

9. Marcus and Olson et al. disclose the essential features of the claimed invention as described above except for a parameter includes identifying a centroid (claim 15) and a signal is a function of temperature (claim 19) and an impedance (claim 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a centroid, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). (See MPEP 2144.05). Additionally, it is well known in the art that a signal is a function of temperature and an impedance to provide a diversity of signal acquisition techniques to realize efficient and effective ways to optimize device operation for successful therapy administration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Marcus and Olson et al. to include a signal is a function of temperature and an impedance to provide optimum device function for administering successful therapy.

10. Marcus discloses accessing stored sample data (claim 27) (e.g. column 6, lines 44–48) and reconstructing a sampled series by connecting adjacent characteristic points with a polynomial equation (claim 39) and a cubic spline equation (claim 40) (column 5, line 29 where the polynomial function includes ... a cubic spline function as per the Applicant's specification).

11. With respect to claims 28–35, Marcus discloses the essential features of the claimed invention as described above except for the features for storing a repetition marker and storing a difference marker as set forth in these claim limitations. However, Olson et al. disclose the

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features for storing a repetition marker and storing a difference marker as set forth in the present claim limitations as the relationship between template and test IVEGs as detailed in Equation (4) for a repetition marker and Equation (3) for a difference marker and Figs. 8 and 9 for the storing limitations and the corresponding teachings beginning in column 8, line 55 through column 10 line 63 for said equations and figures to provide reliable and diagnostically-useful signal data made accessible to the physician for a more precise interpretation and subsequent diagnosis and therapy. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Marcus to include the features for storing a repetition marker and storing a difference marker as set forth in the present claim limitations, as taught by Olson et al. to render reliable signals for accurate diagnosis and therapy.

12. Marcus and Olson et al. disclose the essential features of the claimed invention as described above except for connecting adjacent characteristic points with line segments (claim 38). However, it is well known in the art to connect adjacent characteristic points with line segments to provide an accurate representation of signal for use in accurate diagnosis of a heart condition and subsequent optimized application of therapy. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Marcus and Olson et al. to include connecting adjacent characteristic points with line segments to generate accurate signals for optimum heart condition diagnosis and subsequent therapy application.

13. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marcus and Olson et al. as applied to claim 14 above, and further in view of Street, U.S. Patent 6,516,219.

14. Olson et al. disclose an electrocardiogram (column 3, line 33) as described above and Marcus discloses identifying a plurality of characteristic points (column 8, lines 16–17). Marcus and Olson et al. do not disclose delivering therapy as a function of a plurality of characteristic points. However, Street discloses delivering therapy as a function of a plurality of characteristic points (column 5, lines 56–63) to ensure accurate and required therapy application. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Marcus and Olson et al. to include delivering therapy as a function of a plurality of characteristic points, as taught by Street to ensure accurate and required therapy application.

Allowable Subject Matter

15. Claims 23 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Wyborny et al., U.S. Patent 5,836,889 discloses connecting adjacent characteristic points with line segments and reconstructing sampled series as a function of area, start time, and end time.

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

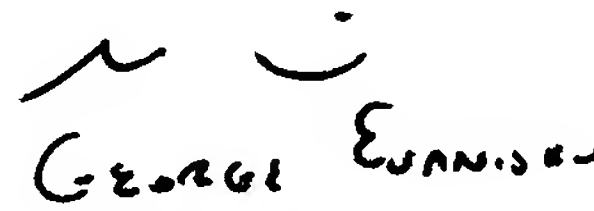
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TLS

November 15, 2006

15 November 2006



George Evers
Primary
11/19/6